

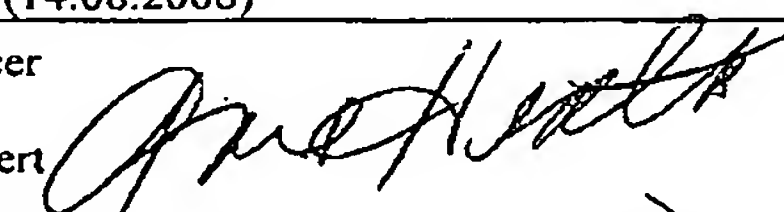

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 34316	FOR FURTHER ACTION		See Form PCT/IPEA/416																								
International application No. PCT/IL06/00346	International filing date (<i>day/month/year</i>) 16 March 2006 (16.03.2006)	Priority date (<i>day/month/year</i>) 17 March 2005 (17.03.2005)																									
International Patent Classification (IPC) or national classification and IPC IPC: A61F 2/00(2006.01) USPC: 600/29																											
Applicant CONTIPI LTD.																											
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of <u>10</u> sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																											
<p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>				<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand 12 March 2007 (12.03.2007)		Date of completion of this report 14 August 2008 (14.08.2008)																									
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer Samuel G. Gilbert  Telephone No. 866-217-9197 																									

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/IL06/00346

Box No. 1 Basis of the report

1. With regard to the **language**, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☐ the international application as originally filed/furnished
- ☒ the description:
 pages 1-55 as originally filed/furnished
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☒ the claims:
 pages 57,59 and 60 as originally filed/furnished
 pages* NONE as amended (together with any statement) under Article 19
 pages* 56,58 and 61-65 received by this Authority on 12 March 2007 (12.03.2007)
 pages* NONE received by this Authority on _____
- ☒ the drawings:
 pages 1/34-34/34 as originally filed/furnished
 pages* NONE received by this Authority on _____
 pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages None
- ☒ the claims, Nos. None
- ☒ the drawings, sheets/figs None
- ☒ the sequence listing (*specify*): None
- ☒ any table(s) related to the sequence listing (*specify*): None

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

5. ☐ This report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 70.2(e)).

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL06/00346**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)

Claims Please See Continuation Sheet

YES

Claims Please See Continuation Sheet

NO

Inventive Step (IS)

Claims Please See Continuation Sheet

YES

Claims Please See Continuation Sheet

NO

Industrial Applicability (IA)

Claims Please See Continuation Sheet

YES

Claims Please See Continuation Sheet

NO

2. Citations and Explanations (Rule 70.7)

Please See Continuation Sheet

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 5, 12, 15, 18, 34-48, 55-58, 63, 65, 68-69, 72-77, 82, 89-90

The opinion as to Novelty was negative (No) with respect to claims 1-4, 6-11, 13-14, 16-17, 19-33, 49-54, 59-62, 64, 66-67, 70-71, 78-81, 83-88

The opinion as to Inventive Step was positive (Yes) with respect to claims 5, 12, 15, 18, 34-48, 55-58, 63, 65, 68-69, 72-77, 82, 89-90

The opinion as to Inventive Step was negative (NO) with respect to claims 1-4, 6-11, 13-14, 16-17, 19-33, 49-54, 59-62, 64, 66-67, 70-71, 78-81, 83-88

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-90

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

V. 2. Citations and Explanations:

Claims 1-4, 6-11, 13-14, 16, 17, 19-33, 49-54, 59-61, 64, 66-67, 70-71, 78-81, and 83-88 lack novelty under PCT Article 33(2) as being anticipated by Ziv (WO 2004/103213)

Ziv teaches an apparatus for treating urinary incontinence, comprising:

a support section that is flexible and is adapted for providing urethral support;

an anchoring section for resisting movement of said apparatus;

an insert, a portion of which is adapted to be positioned proximal to said support section;

a cover that substantially encapsulates said apparatus which also expands in response to movement by the insert and therefore can be considered part of the support section;

a removal device that changes the apparatus from a first stable position wherein the device is insertable and removable, to a second stable position wherein the device provides support to the urethra;

wherein said apparatus is flexible;

wherein said insert selectively provides at least support to said support section of said apparatus;

wherein said insert is adapted to provide pressure to said support section causing expansion of said support section which is cylindrical and thus expands radially; wherein a portion of said insert is elastic whereby the deformation of the elastic portion provides pressure to expand said support section;

wherein said support section is comprised of at least one support arm shaped like a tube;

wherein said insert is comprised of at least a supporting protrusion and a locking protrusion and

wherein said apparatus is inserted so that pressure is applied internally to provide mid-urethral support.

Further, an apparatus for treating urinary incontinence comprising:

Supplemental Box

a support section adapted to render mid-urethral support which is cylindrical and is considered to be a support arm;
an anchoring section which inherently resists movement of said apparatus;
a removal device;
a cover that substantially encapsulates said apparatus;
wherein the entire device is inserted and is therefore considered to be an insert comprising a first material which exhibits first material properties and at least a second material making up a tensile element or resilient support member, wherein the second material exhibits second material properties including elasticity and flexibility, wherein the insert selectively expands said support section;
wherein the first material is a fibrous material and is layered with the second material the combination of which is elastic and flexible in order to provide comfort and support during movement of the user;
wherein the second material can also be considered to be an insert that is positioned proximal to and provides support to said support section;
wherein said support section is flared and wherein the general shape of the entire device is conical;
wherein the two materials of the insert are different sizes and are rolled or folded together such that they are considered to be geometrically interlocking elements; and
wherein the second material or resilient support member biases the support section away from a central axis of said apparatus;
wherein the layers of said insert are a plurality of components removably fitted together.

Ziv also teaches an apparatus capable of being used to treat urinary incontinence, comprising:
a central node that is a rolled sheet or flexible membrane and is considered a bi-stable component as it provides structures to prevent movement in an x and y direction; and
a plurality of protrusions for both support and for anchoring, located on said node;
a removal device or pull-string attached to said bi-stable component for changing the apparatus from a second stable position to a first stable position;
wherein the apparatus has said first stable position wherein the apparatus is external to the user and said second stable position wherein the apparatus is internal to the user and said protrusions are expanded to render support;
wherein the plurality of protrusions or arms is a support section.

Ziv further teaches an apparatus capable of being used to treat urinary incontinence, comprising:
a connector and
a plurality of scrolling sections;
wherein said connector is flexible as it is made of flexible material wherein said plurality of scrolling sections means two sections as there are two scrolled ends as well as two different scrolled materials, the two scrolled ends being on opposite sides of the connector which encases them.

Applicant's attention is invited to the embodiments of Figures 3, and 11-13.

Ziv teaches an apparatus capable of extending the shelf life of a vaginal insertable device, comprising:
an enclosure adapted for receipt of at least a first portion of said device and vaginal insertion;
a section adapted for receipt of at least a second portion of said device such that said second portion is at least partially expanded;
wherein said section is a flared enclosure that is narrower at one end than the other;
wherein said section is provided with a plurality of slots between petals, the slots being sized and numbered to accommodate said second portion of said device.

Ziv teaches an apparatus for motivating a vaginally insertable device, comprising:
an outer section or plunger, adapted for insertion into an applicator or enclosure;
an inner section or insert, capable of coaxial insertion into and movement within said outer section;
a ring, wherein said ring is located on said outer section such that friction is created by the ring when there is movement of said apparatus relative to said applicator wherein said outer section or plunger is substantially located within said applicator or enclosure during storage and
wherein said insert is attached to a removal device.

Claim 5 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence, comprising: a support section, an anchoring section, an insert adapted to be positioned proximal to said support section and that selectively provides at least support to said support section wherein said insert is an o-ring.

Claim 12 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence, comprising: a support section, an anchoring section, an insert adapted to be positioned proximal to said support section and that selectively provides at least support to said support section wherein said insert is an invertible membrane.

Claim 15 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence, comprising: a support section, an anchoring section, an insert adapted to be positioned proximal to said

Supplemental Box

support section and that selectively provides at least support to said support section wherein said insert is an resilient support member that biases at least said support section towards a central axis of said apparatus.

Claim 18 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence, comprising: a support section, an anchoring section, an insert adapted to be positioned proximal to said support section and that selectively provides at least support to said support section wherein said support section and anchoring section are comprised of at least 2 arms with a folding section.

Claims 34-40 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence, comprising: a support section, an anchoring section, at least one expander node provided with at least one expander connected to said apparatus, an elastic member that passes through said at least one expander node and a removable safety catch provided to an expanded end of said elastic member which prevents expanded end from passing through said at least one expander node, wherein said elastic member is substantially unstretched.

Claims 41-48 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence, comprising a support section, an anchoring section, a first groove, and an elastomeric ring positioned on an exterior surface of said apparatus within said first groove, wherein said elastomeric ring provides compression forces to at least a portion of said apparatus.

Claims 55-58 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence comprising a support section having a plurality of support arms, a removal device, and a bi-stable component that is a locking element or a ring slidable on an exterior of said apparatus from a first groove to a second groove; wherein the apparatus is movable from a first stable position associated with said first groove to a second stable position associated with said second groove.

Claim 63 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence comprising a support section and an insert comprising a first material which exhibits first material properties and at least a second material which exhibits second material properties, wherein said insert expands said support section and wherein said second material is more rigid than the support section.

Claim 65 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence comprising a central node that is a rolled sheet, a plurality of support protrusions located on said node and a plurality of anchor protrusions also located on said node wherein said central node has a larger diameter on one end than the other end when rolled.

Claims 68 and 69 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for treating urinary incontinence comprising a connector and a plurality of scrolling sections wherein said scrolling sections are provided with a plurality of protrusions for rendering urethral support or anchoring.

Claim 72-77 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus for inserting a vaginal device comprising an enclosure and a lubricating element located externally of said enclosure, wherein said lubricating element is a ring located around a circumference of said enclosure.

Claim 82 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest an apparatus comprising an enclosure adapted for receipt of at least a first portion of a vaginally insertable device and vaginal insertion, and a section adapted for receipt of at least a second portion of said device such that said second portion is at least partially expanded, wherein the apparatus further comprises a slidable sleeve located externally of said enclosure for repositioning said second portion of said device prior to insertion of said device into a user.

Claims 89 and 90 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a collapsible apparatus for inserting a vaginal device comprising an enclosure and a plunger adapted to coaxially first within said enclosure, an insert provided to said vaginal device, wherein said insert is attached to a removal/activator device; wherein said removal/activator device is removably latched to the plunger and wherein movement of the plunger out of the enclosure moves said insert at least partially through the vaginal device.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. /
PCT/IL06/00348

Supplemental Box

WO 2004/103213 A1 (ELAN ZIV) 02 December 2004. See entire document.